K012630

ALLIANCE
MEDICAL CORPORATION

NOV 0 9 2001

PART B: 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

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Contact: Don Selvey
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(480) 763-5300

Date of preparation: August 10, 2001

Name of device: Trade/Proprietary Name: Reprocessed Arthroscopic Burs
Common or Usual Name: Arthroscopic Bur
Classification Name: Arthroscope

Reprocessed devices:

Manufacturer	Description	Model
Linvatec Corporation	Oval Bur	C9101
Linvatec Corporation	Oval Bur	C9102
Linvatec Corporation	Oval Bur Left Helix	C9106
Linvatec Corporation	Spherical Bur	C9110
Linvatec Corporation	Spherical Bur	C9111
Linvatec Corporation	Spherical Bur	C9112
Linvatec Corporation	Vortex Router	C9131
Linvatec Corporation	Vortex Router Unhooded	C9134
Linvatec Corporation	Oval Bur	H9101
Linvatec Corporation	Oval Bur	H9102
Linvatec Corporation	Spherical Bur	H9110
Linvatec Corporation	Vortex Router Hooder	H9131
Linvatec Corporation	Vortex Router	H9132

Predicate device(s):

K940515	Linvatec® Merlin Polyblade Shavers
K971059	Linvatec® Universal Drive System
K981269	Linvatec® Universal Drive System
K981636	Linvatec® Integrated Drive/Pump System
K990524	Linvatec® E9000 System

Device description: Arthroscopic shavers can be used to abrade, cut and excise tissue and bone; remove loose fragments; and, shave away debris in arthroscopic surgeries, as well as surgeries of the jaw and sinuses.

The arthroscopic shaver components reprocessed by Alliance Medical Corporation include a bur or blade at the end of a long rod that rotates within a long hollow stainless steel housing.

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The housing has a window cut out on one side of the distal end, allowing the bur to cut one structure, while the adjacent one is still protected by the housing on the opposite side of the bur or blade. This system attaches to a motorized handpiece that drives the internal bur or blade inside the outer housing and provides suction to pull the cut tissue and/or bone away from the surgical site.

Intended use:

Reprocessed Arthroscopic Shavers are intended to resect tissue and bone found in articular body cavities during orthopedic, maxillofacial, hand, foot and plastic surgery in patients requiring arthroscopic or orthopedic surgery.

Indications statement:

Reprocessed arthroscopic shavers are indicated for use in orthopedic surgical procedures of the joints, jaw or sinuses where the cutting and removal of soft and hard tissue or bone is needed in patients requiring orthopedic surgery.

Technological characteristics:

The design, materials, and intended use of the Reprocessed Arthroscopic Burs are identical to the predicate devices. The mechanism of action of the Reprocessed Arthroscopic Bur is identical to the predicate devices in that the same standard mechanical design, materials, shapes and sizes are utilized. There are no changes to the claims, intended use, clinical applications, patient population, performance specifications, or method of operation.

Performance data:

Bench and laboratory testing was conducted to demonstrate performance (safety and effectiveness) of the Reprocessed Arthroscopic Burs.

- Biocompatibility
- Validation of reprocessing
- Function Test(s)

Performance testing demonstrates that Reprocessed Arthroscopic Burs perform as originally intended.

Conclusion:

In accordance with the Federal Food, Drug and Cosmetic Act 21 CFR Part 807 and based on the information provided in this premarket notification, Alliance Medical Corporation concludes that the modified device (the Reprocessed Arthroscopic Bur) is safe, effective and substantially equivalent to the predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 0 9 2001

Mr. Don Selvey
Regulatory Affairs
and Quality Assurance
Alliance Medical Corporation, Inc.
10232 South 51st Street
Phoenix, Arizona 85044

Re: K012630
Trade/Device Name: Reprocessed Linvatec Arthroscopic Burs
Regulation Number: 888.1100
Regulation Name: Arthroscope
Regulatory Class: II
Product Code: HRX
Dated: August 10, 2001
Received: August 13, 2001

Dear Mr. Selvey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

II. Indications for Use Statement

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510(k) Number (if known): K012630

Device Name: Alliance Medical Corporation Reprocessed [device name]

Indications for Use: Reprocessed Arthroscopic Shavers are indicated for use in orthopedic surgical procedures of the joints, jaw or sinuses where the cutting and removal of soft and hard tissue or bone is needed in patients requiring orthopedic surgery.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

Prescription Use ✓ (per 21 CFR 801.109) OR Over-the-Counter Use ____

510(k) Number K012630